



PATENT
Attorney Docket No. 101.0050-00000
Customer No. 22882
Express Mail Label No. ET692326237US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Gary K. Michelson)
)
Serial No.: 08/484,928)
)
Filed: June 7, 1995)
)
For: FRUSTO-CONICAL INTERBODY)
SPINAL FUSION IMPLANTS)

Group Art Unit: 3731

Examiner: D. Reip

Confirmation No. 5055

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Further to the Information Disclosure Statements filed July 9, 1997; December 19, 1997; January 14, 1999; June 30, 1999; November 3, 1999; December 5, 2000, and pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached Form PTO-1449. This Information Disclosure Statement is being filed within three months of the filing date of the Request to Withdraw Finality under 37 C.F.R § 1.129(a) of the above-referenced application.

A copy of the following listed documents are enclosed:

1. English language abstract is attached for DE 4302397 (previously submitted).
2. U.S. 3,719,186
3. Cloward, Ralph B.; Surgical Techniques for Lumbar Disc Lesions; Codman; Signature Serial 3.
4. Cloward, Ralph B.; Ruptured Cervical Intervertebral Discs: Removal of Disc & Osteophytes & Anterior Cervical Interbody Fusion (A.C.I.F.); Codman; Signature Series 4.
5. Cloward, Ralph B.; Recent Advances in Surgery of the Cervical Spine; pp. 285-293; German Society For Neurosurgery: Volume 2 Cervical Spine Operations; Excerpta Medica.

6. Hutter, Charles George; Spinal Stenosis and Posterior Lumbar Interbody Fusion; pp. 103-114; Clinical Orthopaedics and Related Research; No. 193; The Association of Bone and Joint Surgeons.
7. Lin, Paul M.; Posterior Lumbar Interbody Fusion; pp. 114-122; Charles C. Thomas; Springfield, Illinois.
8. Lin, Paul M.; Lumbar Interbody Fusion: Principles and Techniques in Spine Surgery; Techniques and Complications; pp. 81, 98, 120, 146, 173, 180-184, 204, 224, 225, 231; Aspen Publishers, Inc.; 1989.
9. Tan, S.B.; A Modified Technique of Anterior Lumbar Fusion with Femoral Cortical Allograft; pp. 83-93; The Journal of Orthopaedic Surgical Techniques, Volume 5, No. 3, 1990.
10. Muller, M.E.; Manual of Internal Fixation: Techniques Recommended by the AO Group; Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979.
11. Hierholzer, G.; Manual on the AO/ASIF Tubular External Fixator; pp. 85-91; Springer-Verlag; 1985.
12. Heim, Urs; Small Fragment Set Manual: Technique Recommended by the ASIF-Group; pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974.
13. Harmon, Paul H.; Anterior Excision and Vertebral Body Fusion Operation for Intervertebral Disk Syndromes of the Lower Lumbar Spine: Three- to Five-Year Results in 244 Cases; pp. 107-127; Clinical Orthopaedics and Related Research, No. 26, J.B. Lippincott Company, 1963.
14. Harmon, Paul H.; A Simplified Surgical Technic for Anterior Lumbar Discectomy and Fusion; Avoidance of Complications; Anatomy of the Retroperitoneal Veins; pp. 130-143; Clinical Orthopaedics and Related Research, No. 37, J.B. Lippincott Company, 1964.
15. Bullough, Peter G.; Atlas of Spinal Diseases; Figure 5.7; J.B. Lippincott Company; 1988
16. Canale, S. Terry; Campbell's Operative Orthopaedics; Volume 3, 9th Edition; pp. 2191, 2216, 2459; Mosby, 1998.

Copies of the remaining listed documents were previously submitted and/or cited in the Information Disclosure Statements dated July 9, 1997; December 19, 1997; January 14, 1999; June 30, 1999; November 3, 1999; and or December 5, 2000, or in a prior application Serial No. 08/396,414, now U.S. Patent No. 6,080,155; application Serial No. 08/074,781, now U.S. Patent No. 5,484,437; application Serial No. 07/968,240, now U.S. Patent No. 5,741,253; application Serial No. 07/698,674, now abandoned; and/or application Serial No. 07/205,935, now U.S. Patent No. 5,015,247; upon which applicant relies for the benefits provided in 35 U.S.C. § 120.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

The present application Serial No. 08/484,928 is a continuation-in-part of application Serial No. 08/396,414, now U.S. Patent No. 6,080,155, which is a continuation-in-part of application Serial No. 08/074,781, now U.S. Patent No. 5,484,437, which is a continuation-in-part of application Serial No. 07/968,240, now U.S. Patent No. 5,741,253, which is a continuation of application Serial No. 07/698,674, now abandoned, which is a divisional of application Serial No. 07/205,935, now U.S. Patent No. 5,015,247.

Applicant brings to the Examiner's attention that the '253 patent, the '437 patent, and U.S. Patent No. 6,096,038 (a divisional of the '437 patent) were the subject of litigation in the United States District Court for the Western District of Tennessee, Western Division, Case No. 99-2656GV, hereinafter referred to as Litigation 3 ("Lit. 3"). The claims of the '437 patent are generally directed to a method for inserting an implant. The claims of the '038 patent are generally directed to instruments used for preparing adjacent vertebrae to receive an implant and/or inserting an implant.

In Litigation 3, the Defendants asserted that various references are pertinent to the issue of validity of the '437 patent, the '253 patent, and the '038 patent under 35 U.S.C. §§ 102 and 103. Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by Defendants in Litigation 3 as being allegedly pertinent to the '437 patent by the designation "Lit. 3a." Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by Defendants in Litigation 3 as being allegedly pertinent to the '253 patent by the designation "Lit. 3b." Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by Defendants in Litigation 3 as being allegedly pertinent to the '038 patent by the designation "Lit. 3c."

The Defendants in Litigation 3 also raised allegations of inequitable conduct in relation to the procurement of:

(1) the '253 patent for failing to (a) highlight U.S. Patent No. 4,570,624 to Wu, (b) disclose litigation related to the '247 patent, and (c) disclose EP 0077159 to Atkins, an article written by Jose Vich ("Anterior cervical interbody fusion with threaded cylindrical bone," *Neurosurg* 63: 750-753, 1985), and manuals by Muller, M.E. ("Manual of Internal Fixation: Techniques Recommended by the AO Group;" Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979), Hierholzer, G. ("Manual on the AO/ASIF Tubular External Fixator;" pp. 85-91; Springer-Verlag; 1985), and Heim, Urs ("Small Fragment Set Manual: Technique Recommended by the ASIF-Group;" pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974);

(2) the '437 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) disclose U.S. Patent No. 2,842,131 to Smith, U.S. Patent No. 4,142,517 to Stavropoulos et al., U.S. Patent No. 4,677,883 to Lee, U.S. Patent No. 4,830,000 to Shutt, U.S. Patent No. 4,878,915 to Brantigan, U.S. Patent No. 4,943,291 to Tanguy, U.S. Patent No. 4,961,740 to Ray et al., and U.S. Patent No. 5,055,104 to Ray; and

(3) the '038 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) filing an allegedly misleading Rule 131 declaration.

Litigation 3, mentioned above, and Litigations 1 and 2, discussed in the Information Disclosure Statement dated January 14, 1999, are no longer pending. The jury in Litigation 2 found all asserted claims of the '253 patent valid in view of the art cited by the defendant. Litigations 1-3 were settled with the defendants in each litigation retracting their assertions of invalidity and inequitable conduct. Discovery documents relating to the aforementioned litigations are available upon request.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant

reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

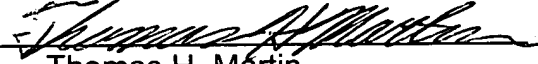
If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP



Date: September 11, 2003

By: 
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09-12-03

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Dear Sir:

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I hereby certify that:

1. Information Disclosure Statement Under 37 C.F.R. § 1.97(b)
2. Form PTO-1449
3. 16 documents
4. Self-addressed return postcard receipt

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service with sufficient postage under 37 C.F.R. § 1.10 on the date indicated above and are addressed to:

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P.O. Box 1450
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Date: September 11, 2003


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